PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P 02 128 WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DK 02/00625	International filing date *(day/month/year)* 24.09.2002	Priority date *(day/month/year)* 24.09.2002
International Patent Classification (IPC) or both national classification and IPC A23G3/30		
Applicant GUMLINK A/S et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 12 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
08.03.2004	03.12.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Kardas-Llorens, E Telephone No. +49 89 2399-8652

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 02/00625

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-11, 13-20	as originally filed
12, 21	received on 05.11.2004 with letter of 03.11.2004

Claims, Numbers

1-48	received on 05.11.2004 with letter of 03.11.2004

Drawings, Sheets

1/2-2/2	received on 05.11.2004 with letter of 03.11.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-48
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-48
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-48
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: WO 01/47368 A (PATEL BHARAT KANAIYALAL ;GOLDBERG DANIEL (US); EATON ROBERT FRANCI) 5 July 2001 (2001-07-05)
D2: EP-A-0 711 506 (UNIV GRONINGEN) 15 May 1996 (1996-05-15)

Novelty:

The present application does meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is new in the sense of Article 33(2) PCT.
A chewing gum comprising biodegradable polymers wherein the number average molecular weight (Mn) is at least 105000 g/mol, is not unambiguously disclosed in any one document cited in the search report.

Inventive step:

The present application does meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-48 involves an inventive step in the sense of Article 33(3) PCT.
Document D1 is directed to gum bases which disclose combination of biodegradable polymers with non-degradable polymers. The resulting chewing gum is not biodegradable.
Document D2 which is directed to chewing gums does not hint to the use of high molecular weight biodegradable polymers for the improvement of textural properties and robustness.
Thus, the presently posed problem which is providing an improved chewing gum texture and which has been solved by increasing the Mn of the biodegradable polymer according to claim 1 has not been made obvious by the disclosures of D1 or D2.

The edible polyester is produced by condensation polymerization reaction of at least one alcohol chosen from the group of trihydroxyl alcohol and dihydroxyl alcohol, and at least one acid chosen from the group consisting of dicarboxylic acid and tricarboxylic acid.

It is possible to use edible or food grade materials. Because the starting acids and alcohols are food grade materials the resultant polymers is edible.

Alcohols: Glycerol, propylene glycol, 1,3 butylene diol

Acids: Citric acid, fumaric acid, adipic acid, malic acid, succinic acid, suberic acid, sebacic acid, dodecanedioic acid, glucaric acid, glutamic acid, glutaric, azelaic acid, tartaric acid

Edible polyesters can replace both elastomers and elastomer plasticizers and form 1-80% of the gum base.

Drawings

The invention will now be described with reference to the drawings of which

fig. 1 illustrates G'(storage modulus) versus oscillation torque for chewing gums 1002, 1003 and 1004, all containing 3% lecithin and where

fig. 2 illustrates tan(delta) versus oscillation torque for chewing gums 1002, 1003 and 1004, all containing 3% lecithin,

Detailed description

In the present context the terms environmentally or biologically degradable polymer compounds refers to chewing gum base components which, after dumping the chewing gum, is capable of undergoing a physical, chemical and/or biological

EXAMPLE 8

An experiment was set up in order to test different chewing gum formulations containing 3% lecithin.

1001 and 1002 are two standard formulations containing elastomers with Mn of 73,000 and 117,000.

1003 is a 100% biodegradable formulation containing elastomer polymer Mn of 65,000 and 1004 is a 100% biodegradable formulation containing elastomer polymer with Mn of 114,000.

The gum centres were chewed in a chewing machine (CF Jansson). The chewing frequency was set to 1 Hz, a pH buffer was used as saliva and the temperature was set at 37°C. The chewing time was set to 30 seconds. After chewing, the chewed cud was measured on a rheometer, type AR1000 from TA Instruments. The oscillation measurement is performed at a stress within the linear viscoelastic region and a temperature of 37°C with a parallel plate system (d=2.0 cm, hatched). G', and tan delta vs. shear rate.

The results are summarised in fig.1 and fig. 2, and as it appears, the biodegradable formulations containing 3% lecithin show different rheological behavior. The low Mn of 65,000 (1003) is very soft and less elastic compared to the formulation with high Mn (1004).
This is confirming the sensorial evaluation described in the above EXAMPLE 7.

Patent Claims

1. Chewing gum comprising at least one biodegradable polymer, wherein the molecular weight of said biodegradable polymer is at least 105000 g/mol (Mn).

2. Chewing gum according to claim 1, wherein the molecular weight of said at least one biodegradable polymer is at least 150000 g/mol (Mn).

3. Chewing gum according to claim 1 or 2, wherein the molecular weight of said at least one biodegradable polymer is within the range of 105000 g/mol (Mn) to 1000000 g/mol (Mn).

4. Chewing gum according to any of the claims 1 to 3, wherein the molecular weight of said at least one biodegradable polymer is within the range of 105000 g/mol (Mn) to 500000 g/mol (Mn).

5. Chewing gum according to any of the claims 1 to 4, wherein the molecular weight of said at least one biodegradable polymer is within the range of 105000 g/mol (Mn) to 350000 g/mol (Mn).

6. Chewing gum according to any of the claims 1 to 5, wherein the molecular weight of said at least one biodegradable polymer is within the range of 105000 g/mol (Mn) to 250000 g/mol (Mn).

7. Chewing gum according to any of the claims 1 to 6, wherein the molecular weight of said at least one biodegradable polymer is less than 2000000 g/mol (Mn).

8. Chewing gum according to any of the claims 1 to 7, wherein the polydispersity of said at least one biodegradable polymer is within the range of 1 to 5.

9. Chewing gum according to any of the claims 1 to 8, wherein the polydispersity of said at least one biodegradable polymer is within the range of 1 to 2.5.

10. Chewing gum according to any of the claims 1 to 9, wherein the at least one biodegradable polymer comprises at least 25% of the chewing gum polymers, preferably at least 50% of the chewing gum polymers.

11. Chewing gum according to any of the claims 1 to 10, wherein all the biodegradable polymers comprised in the chewing gum comprises at least 25%, preferably at least 90% of the chewing gum polymers.

12. Chewing gum according to any of the claims 1 to 10, wherein all the biodegradable polymers comprised in the chewing gum comprises at least 80%, preferably at least 95% of the chewing gum polymers.

13. Chewing gum according to any of the claims 1 to 12, wherein the chewing gum is substantially free of non-biodegradable polymers.

14. Chewing gum according to any of claims 1-13, wherein said chewing gum ingredients comprises flavoring agents.

15. Chewing gum according to any of claims 1-14, wherein said flavoring agents comprises natural and synthetic flavorings in the form of natural vegetable components, essential oils, essences, extracts, powders, including acids and other substances capable of affecting the taste profile.

16. Chewing gum according to any of claims 1-15, wherein said chewing gum comprises flavor in an amount of 0.01 to about 30 wt%, said percentage being based on the total weight of the chewing gum

17. Chewing gum according to any of claims 1-16, wherein said chewing gum comprises flavor in an amount of 0.2 to about 4 wt%, said percentage being based on the total weight of the chewing gum

18. Chewing gum according to any of claims 1-17, wherein said flavor comprises water soluble ingredients.

19. Chewing gum according to any of claims 1-18, wherein said water soluble flavor comprises acids.

20. Chewing gum according to any of claims 1-19, wherein said flavor comprises water insoluble ingredients.

21. Chewing gum according to any of claims 1-20, wherein said chewing gum ingredients comprises sweeteners.

22. Chewing gum according to any of claims 1-21, wherein said sweetener comprises bulk sweeteners

23. Chewing gum according to any of claims 1-22, wherein the chewing gum comprises bulk sweeteners in the amount of about 5 to about 95% by weight of the chewing gum, more typically about 20 to about 80% by weight of the chewing gum.

24. Chewing gum according to any of claims 1-23, wherein said sweetener comprises high intensity sweeteners

25. Chewing gum according to any of claims 1-24, wherein the high intensity sweeteners comprise sucralose, aspartame, salts of acesulfame, alitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizin, dihydrochalcones, thaumatin, monellin, sterioside, alone or in combination

26. Chewing gum according to any of claims 1-25, wherein the chewing gum comprises high intensity sweeteners in an amount of about 0 to about 1% by weight of the chewing gum, more typically about 0.05 to about 0.5% by weight of the chewing gum.

27. Chewing gum according to any of claims 1-26, wherein the chewing gum comprises at least one softener.

28. Chewing gum according to any of claims 1-27, wherein the at least one softener comprises tallow, hydrogenated tallow, hydrogenated and partially hydrogenated vegetable oils, cocoa butter, glycerol monostearate, glycerol triacetate, lecithin, mono-, di- and triglycerides, acetylated monoglycerides, fatty acids - such as stearic, palmitic, oleic and linoleic acids mixtures thereof.

29. Chewing gum according to any of claims 1-28, wherein the chewing gum comprises softeners in the amount of about 0 to about 18% by weight of the chewing gum, more typically about 0 to about 12% by weight of the chewing gum.

30. Chewing gum according to any of claims 1-29, wherein said chewing gum ingredients comprise active ingredients.

31. Chewing gum according to any of claims 1-30, wherein said active ingredients being selected from the group of: Acetaminophen, Acetylsalicylsyre Buprenorphine Bromhexin Celcoxib Codeine, Diphenhydramin, Diclofenac, Etoricoxib, Ibuprofen, Indometacin, Ketoprofen, Lumiracoxib, Morphine, Naproxen, Oxycodon, Parecoxib, Piroxicam, Pseudoefedrin, Rofecoxib, Tenoxicam, Tramadol, Valdecoxib, Calciumcarbonat, Magaldrate, Disulfiram, Bupropion, Nicotine, Azithromycin, Clarithromycin, Clotrimazole, Erythromycin, Tetracycline, Granisetron, Ondansetron, Prometazin, Tropisetron, Brompheniramine, Ceterizin, leco-Ceterizin, Chlorcyclizine, Chlorpheniramin, Chlorpheniramin, Difenhydramine, Doxylamine, Fenofenadin, Guaifenesin, Loratidin, des-Loratidin, Phenyltoloxamine, Promethazin, Pyridamine, Terfenadin, Troxerutin, Methyldopa, Methylphenidate, Benzalcon. Chloride, Benzeth. Chloride, Cetylpyrid. Chloride, Chlorhexidine, Ecabet-sodium, Haloperidol, Allopurinol, Colchinine, Theophylline,

Propanolol, Prednisolone, Prednisone, Fluoride, Urea, Miconazole, Actot, Glibenclamide, Glipizide, Metformin, Miglitol, Repaglinide, Rosiglitazone, Apomorfin, Cialis, Sildenafil, Vardenafil, Diphenoxylate, Simethicone, Cimetidine, Famotidine, Ranitidine, Ratinidine, cetrizin, Loratadine, Aspirin, Benzocaine, Dextrometorphan, Ephedrine, Phenylpropanolamine, Pseudoephedrine, Cisapride, Domperidone, Metoclopramide, Acyclovir, Dioctylsulfosucc., Phenolphtalein, Almotriptan, Eletriptan, Ergotamine, Migea, Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan, Aluminium salts, Calcium salts, Ferro salts, Silver salts, Zinc-salte, Amphotericin B, Chlorhexidine, Miconazole, Triamcinolonacetonid, Melatonine, Phenobarbitol, Caffeine, Benzodiazepiner, Hydroxyzine, Meprobamate, Phenothiazine, Buclizine, Brometazine, Cinnarizine, Cyclizine, Difenhydramine, Dimenhydrinate, Buflomedil, Amphetamine, Caffeine, Ephedrine, Orlistat, Phenylephedrine, Phenylpropanolamin, Pseudoephedrine, Sibutramin, Ketoconazole, Nitroglycerin, Nystatin, Progesterone, Testosterone, Vitamin B12, Vitamin C, Vitamin A, Vitamin D, Vitamin E, Pilocarpin, Aluminiumaminoacetat, Cimetidine, Esomeprazole, Famotidine, Lansoprazole, Magnesiumoxide, Nizatide and/or Ratinidine or derivates and mixtures thereof.

32. Chewing gum according to any of claims 1-31, wherein the chewing gum is substantially free of non-biodegradable polymers

33. Chewing gum according to any of claims 1-32, wherein the at least one biodegradable polyester copolymer obtained by the polymerization of one or more cyclic esters by ring-opening and where at least one of the cyclic esters are selected from the groups of glycolides, lactides, lactones, cyclic carbonates or mixtures thereof.

34. Chewing gum according to any of claims 1-33, wherein lactone monomers are chosen from the group of ε-caprolactone, δ-valerolactone, γ-butyrolactone, and β-propiolactone. It also includes ε-caprolactones, δ-valerolactones, γ-butyrolactones, or β-propiolactones that have been substituted with one or more alkyl or aryl

substituents at any non-carbonyl carbon atoms along the ring, including compounds in which two substituents are contained on the same carbon atom.

35. Chewing gum according to any of claims 1-34,
wherein the carbonate monomer is selected from the group of trimethylene carbonate, 5-alkyl-1,3-dioxan-2-one, 5,5-dialkyl-1,3-dioxan-2-one, or 5-alkyl-5-alkyloxycarbonyl-1,3-dioxan-2-one, ethylene carbonate, 3-ethyl-3-hydroxymethyl, propylene carbonate, trimethylolpropane monocarbonate, 4, 6dimethyl-1, 3-propylene carbonate, 2, 2-dimethyl trimethylene carbonate, and 1, 3-dioxepan-2-one and mixtures thereof.

36. Chewing gum according to any of claims 1-35,
wherein cyclic ester polymers and their copolymers resulting from the polymerization of cyclic ester monomers include, but are not limited to: poly (L-lactide) ; poly (D-lactide) ; poly (D, L-lactide) ; poly (mesolactide) ; poly (glycolide) ; poly (trimethylenecarbonate) ; poly (epsilon-caprolactone) ; poly (L lactide-co-D, L-lactide) ; poly (L-lactide-co-meso-lactide) ; poly (L-lactide co-glycolide) ; poly (L-lactide-co-trimethylenecarbonate) ; poly (L-lactide co-epsilon-caprolactone) ; poly (D, L-lactide-co-meso-lactide) ; poly (D, L lactide-co-glycolide) ; poly (D, L-lactide-co-trimethylenecarbonate) ; poly (D, L-lactide-co-epsilon-caprolactone) ; poly (meso-lactide-co glycolide) ; poly (meso-lactide-co-trimethylenecarbonate) ; poly (meso lactide-co-epsilon-caprolactone) ; poly (glycolide-cotrimethylenecarbonate) ; poly (glycolide-co-epsilon-caprolactone).

37. Chewing gum according to any of claims 1-36,
wherein the chewing comprises filler.

38. Chewing gum according to any of claims 1-37,
wherein the chewing gum comprises filler in an amount of about 0 to about 50% by weight of the chewing gum, more typically about 10 to about 40% by weight of the chewing gum.

39. Chewing gum according to any of claims 1-38, wherein the chewing gum comprises at least one coloring agent.

40. Chewing gum according to any of claims 1-39, where the chewing gum is coated with an outer coating.

41. Chewing gum according to any of claims 1-40, wherein the outer coating is a hard coating.

42. Chewing gum according to any of claims 1-41, wherein the hard coating is a coating selected from the group consisting of a sugar coating and a sugarless coating and a combination thereof.

43. Chewing gum according to any of claims 1-42, wherein the hard coating comprises 50 to 100% by weight of a polyol selected from the group consisting of sorbitol, maltitol, mannitol, xylitol, erythritol, lactitol and isomalt.

44. Chewing gum according to any of claims 1-43, wherein the outer coating is an edible film comprising at least one component selected from the group consisting of an edible film-forming agent and a wax.

45. Chewing gum according to any of claims 1-44, wherein the film-forming agent is selected from the group consisting of a cellulose derivative, a modified starch, a dextrin, gelatine, shellac, gum arabic, zein, a vegetable gum, a synthetic polymer and any combination thereof.

46. Chewing gum according to any of claims 1-45, wherein the outer coating comprises at least one additive component selected from the group consisting of a binding agent, a moisture absorbing component, a film forming agent, a dispersing agent, an antisticking component, a bulking agent, a flavouring agent, a colouring agent, a pharmaceutically or cosmetically active component, a lipid component, a

wax component, a sugar, an acid and an agent capable of accelerating the after-chewing degradation of the degradable polymer.

47. Chewing gum according to any of claims 1-46, wherein the outer coating is a soft coating.

48. Chewing gum according to any of claims 1-47, wherein the soft coating comprises a sugar free coating agent.

49. Chewing gum according to any of the claims 1-48, wherein said chewing gum comprises

at least one biodegradable elastomer in the amount of about 0.5 to about 70% wt of the chewing gum,

at least one biodegradable plasticizer in the amount of about 0.5 to about 70% wt of the chewing gum and

at least one chewing gum ingredient chosen from the groups of softeners, sweeteners, flavoring agents, active ingredients and fillers in the amount of about 2 to about 80% wt of the chewing gum.

50. Method of increasing the robustness of chewing gum comprising at least one biodegradable polymer by increasing the molecular weight of the at least one biodegradable polymer.

51. Method of increasing the robustness according to claim 50, whereby the molecular weight of said biodegradable polymer is adjusted to be at least 105000 g/mol (Mn).

52. Method of increasing the robustness according to claim 50 or 51, whereby the molecular weight of said biodegradable polymer is adjusted to be at least 150000 g/mol (Mn).

53. Method of increasing the robustness according to any of the claims 50 -52, whereby the molecular weight of said biodegradable polymer is adjusted to be at least 250000 g/mol (Mn).

54. Method of increasing the robustness according to any of the claims 50 -53, whereby the molecular weight of said at least one biodegradable polymer is adjusted to be within the range of 105000 g/mol (Mn) to 500000 g/mol (Mn).

55. Method of increasing the robustness according to any of the claims 50 -52, whereby the molecular weight of said at least one biodegradable polymer is adjusted to within the range of 105000 g/mol (Mn) to 350000 g/mol (Mn).

56. Method of increasing the robustness according to any of the claims 50 -55, whereby the molecular weight of said at least one biodegradable polymer is adjusted within the range of 105000 g/mol (Mn) to 250000 g/mol (Mn).

57. Method of increasing the robustness according to any of the claims 50 -56, whereby the molecular weight of said at least one biodegradable polymer is adjusted to be less than 2000000 g/mol (Mn).

58. Gum base according to any of claims 1-57.

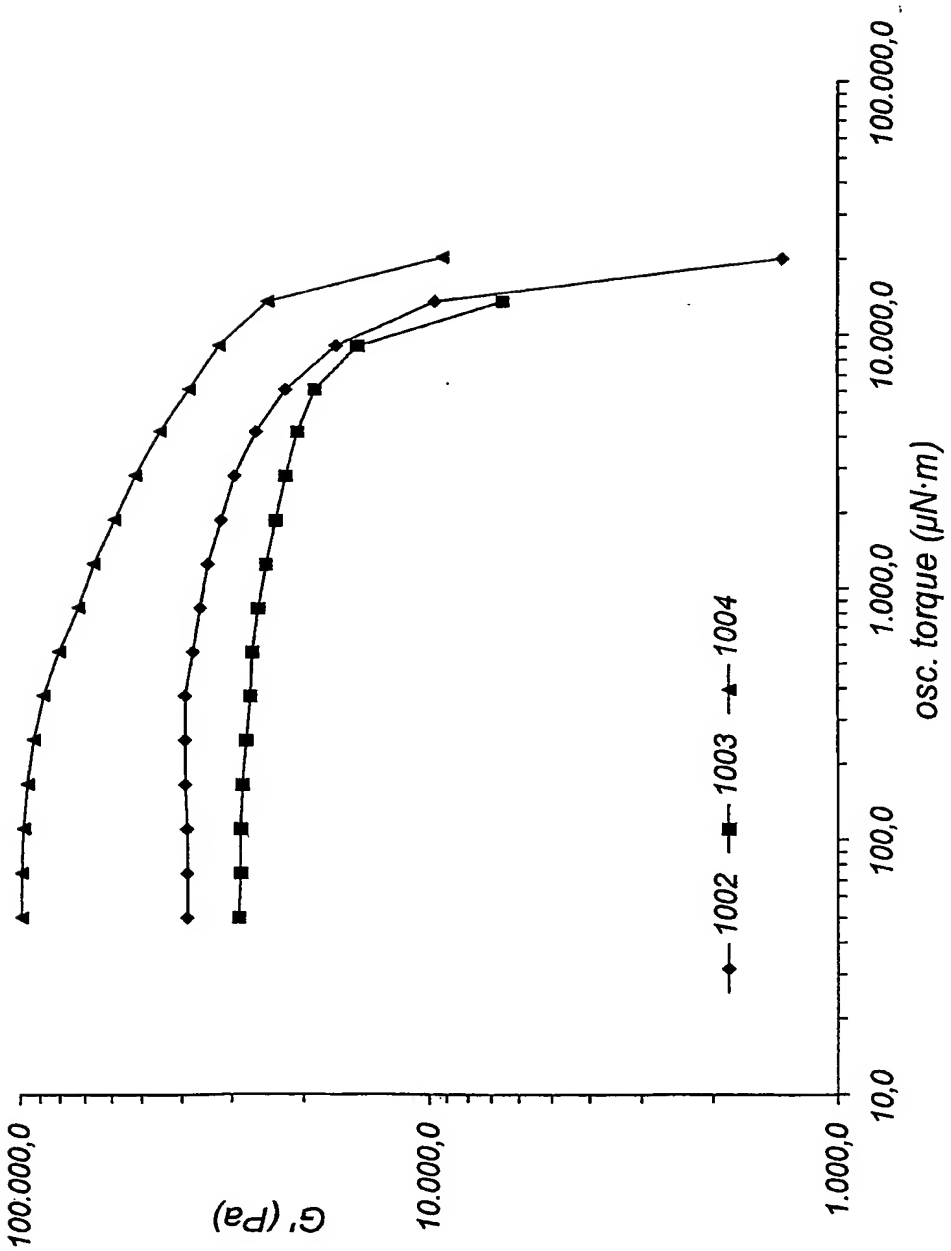

Fig. 1

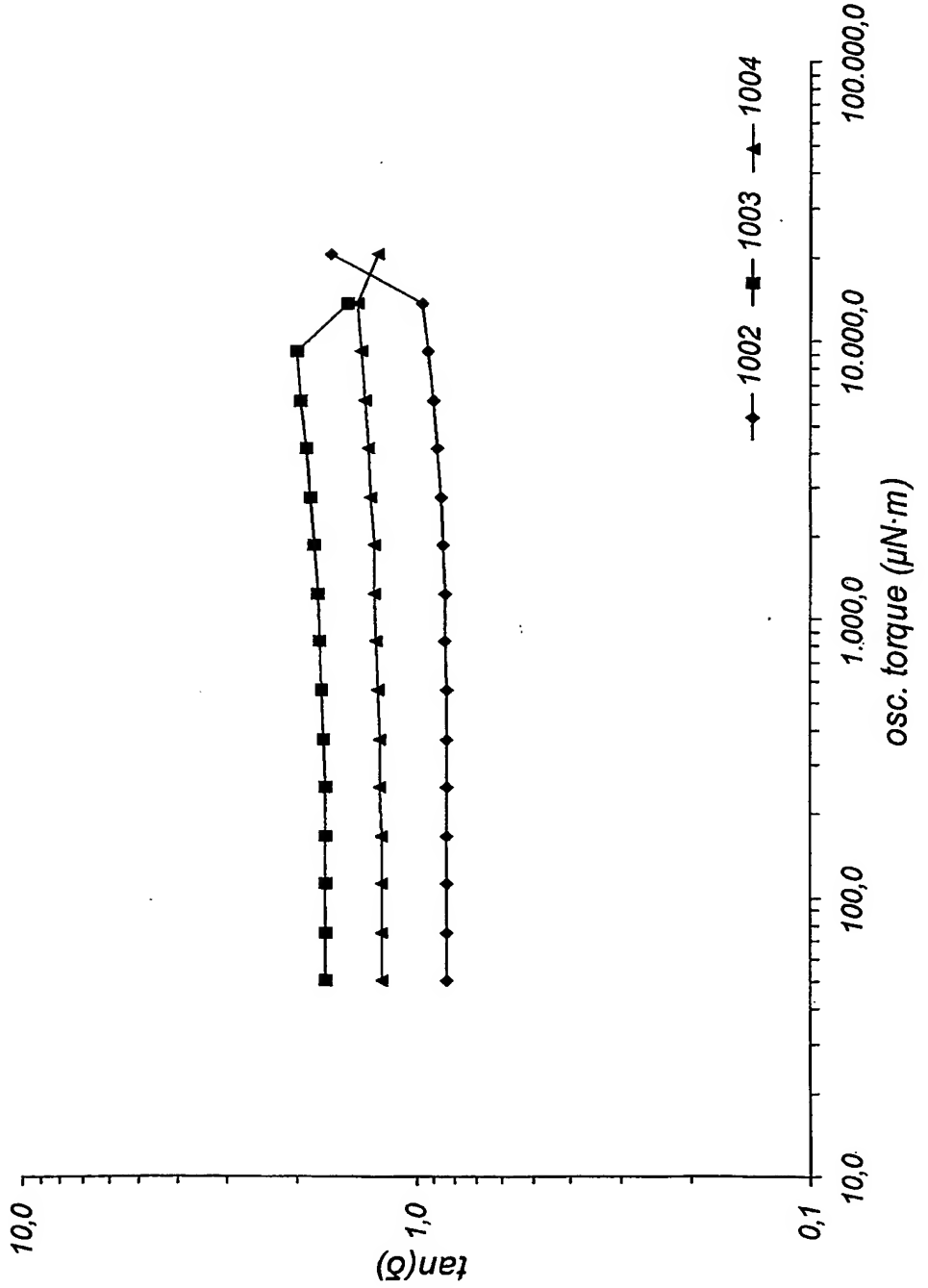
1002
1003
1004
100.000,0
10.000,0
1.000,0
100,0
10,0
osc. torque (µN·m)
10,0
1,0
0,1
tan(δ)

Fig. 2